UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

KIM BERTOLINI-MIER and ROGER MIER,	)	
Plaintiffs,	)	
v.	)	Case No. 5:16-cv-35
UPPER VALLEY NEUROLOGY NEUROSURGERY, P.C., and DONALD W. AYRES, M.D.,	)	
Defendants.	)	

DECISION ON MOTION FOR PROTECTIVE ORDER
(Doc. 96)

In this diversity action, Plaintiffs Kim Bertolini-Mier and her husband Roger Mier have sued Upper Valley Neurology Neurosurgery, P.C. ("UVNN"), UVNN physician Dr. Donald W. Ayres, and Alice Peck Day Memorial Hospital ("APD") for medical malpractice and loss of consortium. They allege that, between 2007 and 2011, APD improperly administered and interpreted radiologic studies as indicating that Ms. Bertolini-Mier suffered from multiple sclerosis ("MS"). (*See* Doc. 8 ¶ 12.) According to the Amended Complaint, Dr. Ayres determined that Ms. Bertolini-Mier "might not reach research criteria for diagnosis" based on the tests that were done, but nevertheless made the diagnosis of "highly probable" MS. (*Id.* ¶ 13.)

Plaintiffs allege that, from 2007 until May 2014, Dr. Ayres treated Ms. Bertolini-Mier with a series of MS drugs, including the powerful drug Tysabri (natalizumab) beginning in April 2011. (*Id.* ¶¶ 14–15.) Plaintiffs further allege that Dr. Ayres stood by his diagnosis and treatment plan despite being aware that other medical providers questioned the MS diagnosis and the administration of Tysabri. (*Id.* ¶¶ 16–17.) Also according to the Amended Complaint, between 2007 and May 2014, Dr. Ayres was conducting "trials" of Tysabri for which he was

compensated by pharmaceutical manufacturer Biogen, and Ms. Bertolini-Mier was a subject of that trial without her knowledge. (*Id.* ¶¶ 18–19.) Plaintiffs allege that Ms. Bertolini-Mier suffered a neurological event in May 2014 that required extended hospitalization and that she has required ongoing treatment since her discharge. (*Id.* ¶ 20.)

The court dismissed the claims against APD for lack of personal jurisdiction on September 13, 2017. (Doc. 51.) The remaining parties have since engaged in extensive discovery, as evidenced by numerous discovery certificates filed in 2017–2019. Currently pending is UVNN's September 23, 2019 Motion for a Protective Order under Fed. R. Civ. P. 26(c). (Doc. 96.) Plaintiffs oppose the motion. (Doc. 99.) UVNN filed a reply on October 11, 2019. (Doc. 101.)

Background

Plaintiffs served UVNN with a notice of deposition under Fed. R. Civ. P. 30(b)(5) and (6) on June 18, 2019. (Doc. 96-5.) The notice seeks testimony regarding "[t]he number of patients to whom Tysabri was administered by any provider associated with UVNN between 2007 and 2014." (*Id.* at 4.) It also seeks testimony regarding the following subjects:

> a. the relationship between Ayres & Associates Clinical Trials and UVNN;
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> b. the clinical trials and studies performed by Ayres & Associates Clinical Trials or by UVNN between 2007 and 2014;
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> c. the UVNN agents or employees who performed work of any sort under the name, or auspices of Ayres & Associates Clinical Trials between 2007 and 2014;
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> d. the persons who maintained records, including records of clinical trials, persons involved, companies involved, and financial records for Ayres & Associates Clinical Trials between 2007 and 2014;
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> e. the Consideration (as defined in Plaintiffs' Second Set of Interrogatories and Requests to Produce) provided to UVNN, Ayres & Associates Clinical Trials, or any of its agents or representatives for work done under the name, or auspices of Ayres & Associates Clinical Trials between 2007 and 2014;

> f. the entities which provided Consideration to UVNN or Ayres & Associates Clinical Trials, or any of its agents or representatives for work done under the name, or auspices of Ayres & Associates Clinical Trials between 2007 and 2014;
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> g. [t]he records of time, expense, and Consideration provided to UVNN or Ayres & Associates Clinical Trials, or any of its agents or representatives for work done under the name, or auspices of Ayres & Associates Clinical Trials between 2007 and 2014 . . . .

(*Id.* at 3–4.)

UVNN asserts that the evidence produced in discovery proves that Dr. Ayres and UVNN never conducted or participated in a "clinical trial" of Tysabri. Instead, UVNN states that Ms. Bertolini-Meir consented to participate in a voluntary observational study of individuals receiving or considering Tysabri treatment for relapsing MS. (*See* Doc. 96-4 (consent forms signed by Ms. Bertolini-Mier on January 24, 2011 and April 24, 2012).) The "observational, longitudinal cohort study"—dubbed "Stratify-2"—was sponsored by Biogen, but the study itself involved no treatment or intervention; it consisted instead only of blood testing of participants with relapsing MS who received commercial natalizumab. (*See id.* at 3 ("Only the cost of the antibody test will be paid for by Biogen Idec. Expenses related to your therapies, such as doctor charges, other office visits, or other tests are not covered under this study.").) *See also JC Virus Antibody Study of Participants with Relapsing Forms of MS Receiving Treatment with Natalizumab (STRATIFY-2)*, U.S. Nat'l Library of Med., https://clinicaltrials.gov/ct2/show/NCT01070836 (accessed Oct. 29, 2019).[1]

[1] The stated purpose of Stratify-2 was "to better understand whether antibodies to JCV [the "JC virus"] may be used to predict whether a patient is at higher or lower risk for developing PML [Progressive Multifocal Leukoencephalopathy]." (Doc. 96-4 at 2.) The study offered "no direct health benefits" to participants, but according to the consent form, information collected from the study "may help Biogen Idec and your doctor better understand JCV and risk factors for developing PML." (*Id.* at 3.)

UVNN represents that it has already produced three categories of information to Plaintiffs. Those three categories are: (1) "[a]ll documents in UVNN's possession, custody and control regarding Stratify-2"; (2) "[t]estimony by Dr. Ayres and CMA Chipman regarding the Stratify-2 study and records related to the study"; and (3) "[t]he titles and years of all medical studies and clinical trials in which UVNN or Dr. Ayres ever participated 'for [MS] medications' and the titles and years of all medical studies and clinical trials in which UVNN or Dr. Ayres participated from 2007 through 2014 'involving medications of any kind, whether or not used to treat MS.'" (Doc. 96 at 6 (final alteration in original; footnotes omitted).)

Plaintiffs state that they "do not believe" the list of studies that Defendants have produced is complete. (Doc. 99 at 5 n.2.) More generally, Plaintiffs argue that their Rule 30(b)(6) notice was motivated by other evidence revealed in discovery. They note Dr. Ayres's testimony that "Ayres & Associates Clinical Trials" is "[a] d/b/a under UVNN" that received compensation for its work conducting clinical trials for drug companies. (Doc. 99-2 at 3.) When asked whether Ayres & Associates Clinical Trials had done other studies for Biogen prior to Stratify-2, Dr. Ayres stated, "I don't know." (*Id.* at 7.) He remarked, "[w]e did a lot of studies." (*Id.* at 8.)

Plaintiffs also point to a 2005 edition of a National Multiple Sclerosis Society publication in which Ayres & Associates Clinical Trials announced a research studying "using an investigational drug for the treatment of patients with relapsing-remitting or secondary progressive Multiple Sclerosis." (Doc. 99-4 at 9.) According to Plaintiffs, this shows that Ayres & Associates Clinical Trials was active in soliciting patients for MS studies.

Analysis

UVNN states that it has already produced documents, data, and testimony about Stratify-2 and that it has no objection to providing Rule 30(b)(6) testimony about its participation in

Stratify-2. But UVNN objects to what it perceives is a request in the June 18, 2019 notice of deposition for "testimony, documents, and financial data relating to every other study and clinical trial in which UVNN participated during 2007–2014." (Doc. 96 at 2.) UVNN maintains that such evidence is not relevant to any claim or defense and not proportional to the needs of the case. UVNN requests a protective order limiting the scope of interrogation and document production to UVNN's participation in Stratify-2 and "general information about UVNN's participation in studies and clinical trials" and precluding evidence "related to other studies and clinical trials in which UVNN participated." (*Id.*)

Plaintiffs urge the court to deny UVNN's request. Plaintiffs do not dispute that Ms. Bertolini-Mier was enrolled in Stratify-2. But Plaintiffs insist that their inquiry is broader than that single study. (Doc. 99 at 5.) They maintain that the information they seek is relevant to a "central" question in this case: "[d]etermining why Dr. Ayres and UVNN chose to prescribe, and then hold fast to the prescription of Tysabri." (*Id.* at 7.) According to Plaintiffs, their notice of deposition seeks to "explore whether the decision to administer Tysabri . . . was improperly influenced by the Defendants' relationship with drug companies, including Biogen, the manufacturer of Tysabri." (*Id.* at 1–2.) To do that, according to Plaintiffs, they "must necessarily consider the entirety of the arrangements [Defendants] made with drug companies and the level of compensation they received." (*Id.* at 5.)

I. Rule 26 Standards

Rule 26 defines the general scope of discovery as follows:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b). Under Rule 26(c), "[a] party or any person from whom discovery is sought may move for a protective order in the court where the action is pending." Fed. R. Civ. P. 26(c). "The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." *Id.* Such a protective order may, among other things, "limit[] the scope of disclosure or discovery to certain matters." Fed. R. Civ. P. 26(c)(1)(D).

Rule 26(c) "confers broad discretion on the trial court to decide when a protective order is appropriate and what degree of protection is required." *Patient A v. Vt. Agency of Human Servs.*, No. 5:14-cv-000206, 2016 WL 880036, at *1 (D. Vt. Mar. 1, 2016) (quoting *U.S. Commodity Futures Trading Comm'n v. Parnon Energy Inc.*, 593 F. App'x 32, 36 (2d Cir. 2014)). "If the evidence sought is relevant, 'the burden is upon the party seeking non-disclosure or a protective order to show good cause.'" *Id.* (quoting *Penthouse Int'l, Ltd. v. Playboy Enters., Inc.*, 663 F.2d 371, 391 (2d Cir. 1981)). "Good cause is established by demonstrating a particular need for protection." *Id.* (quoting *Rosas v. Alice's Tea Cup, LLC*, No. 14 Civ. 8788(JCF), 2015 WL 4097947, at *2 (S.D.N.Y. July 6, 2015)); *see also New England Life Ins. Co. v. Wilson*, No. 2:11-cv-45, 2011 WL 13214116, at *4 (D. Vt. Sept. 28, 2011) ("The good cause standard is satisfied by a showing that disclosure will cause a clearly defined, serious injury, substantiated by specific examples or articulated reasoning.").

II. Plaintiffs' Discovery Request in Context

Plaintiffs are not the first to be concerned about improper influence by pharmaceutical manufacturers upon physicians. *See* Richard S. Saver, *Financial Conflicts in the New Era of Sunshine: What We Know & Still Need to Know*, 15 Ind. Health L. Rev. 67, 68 (2018) [hereinafter "*Financial Conflicts*"] ("[F]inancial conflicts of interest in health care have been

long-standing."). Vermont enacted a law relating to the transparency of prescription drug pricing and information after making legislative findings that, among other things, "[t]he one-sided nature of [pharmaceutical] marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate." Vt. Acts No. 80, § 1 (2007).[2] In a multidistrict litigation in 2008, one court remarked that "[t]he medical community appears to be only beginning to grasp the extent and influence of pharmaceutical companies over the medical system and prescribing decisions." *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2008 WL 2696916, at *33 (E.D.N.Y. July 2, 2008).

The federal government took action in 2010 when it enacted the Physician Payments Sunshine Act ("Sunshine Act") as part of the Patient Protection and Affordable Care Act, requiring reporting of industry-medicine financial relationships. *See* 42 U.S.C. § 1320a-7h. According to one commentator in 2018, the Sunshine Act "so far has a very mixed, uneven record." *Financial Conflicts*, 15 Ind. Health L. Rev. at 68. The issue of pharmaceutical manufacturers' influence upon treatment providers continues to generate substantial discussion and commentary.[3]

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[2] The portion of Act 80 codified at 18 V.S.A. § 4631—"section 17" of the Act—was subsequently invalidated upon review in *IMS Health Inc. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010), *aff'd*, 564 U.S. 552 (2011).

[3] *See, e.g.*, Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape & Avenues for Improvement*, 30 Stan. L. & Pol'y Rev. 421, 462 (2019) ("Considerable evidence documents the substantial impact of industry promotion on physician decision-making, including the association between pharmaceutical promotion and non-evidence-based prescribing."); Mary J. Davis, *Time for a Fresh Look at Strict Liability for Pharmaceuticals*, 28 Cornell J. of L. & Pub. Pol'y 399, 433 (2019) (discussing effect of pharmaceutical payments to medical providers on prescribing practices); Lars Noah, *Doctors on*

The Sunshine Act reveals some information about the relationships between the pharmaceutical industry and medical providers, but "[l]imited data exists concerning the effects of financial conflicts in health care decision-making generally and it remains subject to conflicting interpretation." *Financial Conflicts*, 15 Ind. Health L. Rev. at 92. Perhaps it is too early to draw general conclusions from the data that the Sunshine Act has made available. And, in light of numerous "confounding factors," the Sunshine Act data may be insufficient "to resolve definitively the enduring uncertainty about financial conflicts and causation." *Id.* at 95.

III. Relevancy and Proportionality of the Requested Discovery

In this specific case, the disclosures mandated by the Sunshine Act appear to show relatively little about Dr. Ayres's financial relationship with pharmaceutical companies or with Biogen in particular. According to the online database created under the Sunshine Act, the only years for which data is available are 2013 and 2014. The data show that Dr. Ayres received $171 from Biogen Idec on September 17, 2013 in "associated research funding" and that he received five "general payments" from Biogen Idec in 2014 totaling $174.25. *See* https://openpaymentsdata.cms.gov/physician/1310566/summary (accessed Oct. 29, 2019). Plaintiffs argue that they need to examine the entirety of Defendants' financial arrangements with drug companies to determine whether Dr. Ayres was "influenced by his relationships with the drug companies from which he received compensation." (Doc. 99 at 5.) UVNN insists that

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the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers, 66 Buff. L. Rev. 855, 906 (2018) ("Most observers regard offers of financial incentives to select therapeutic products as crossing the line, but the practice has continued in different guises."); Note, Shena T. Wheeler, *Under the Influence: An Examination of the Tactics Pharmaceutical Companies Use to Manipulate Physicians*, 7 Ind. Health L. Rev. 89, 115 (2010) ("Studies have shown that gifts from pharmaceutical companies, pharmaceutical advertisements, and information tendered from pharmaceutical representatives may have an effect on physicians' prescribing habits.").

the requested evidence is not relevant to any claim or defense and is not proportional to the needs of the case.

A. Relevancy

UVNN is correct insofar as it asserts that evidence relating to studies and trials other than Stratify-2 would be irrelevant to a claim that Defendants' receipt of funds for participating in a "drug trial" of Tysabri influenced them to prescribe that medication. Plaintiffs do not dispute that Ms. Bertolini-Mier was not prescribed Tysabri as part of any "drug trial." But Plaintiffs seek discovery on a broader issue: was Dr. Ayres influenced by any relationships with drug companies that involved compensation?

UVNN cites no authority suggesting that evidence on that issue is irrelevant. The court concludes that such evidence is relevant. *See* Lars Noah, *Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers*, 66 Buff. L. Rev. 855, 882 (2018) ("[F]inancial conflicts that bear directly on the choice of treatment certainly should qualify as relevant information."). Indeed, even commentators from the defense bar have suggested that such evidence is likely relevant. *See* Ryan Wood, *Solar Powered Impeachment of Physician-Clients & Experts*, 56 No. 8 DRI For the Defense 36 (Aug. 2014) (discussing admissibility and concluding that defendants must prepare witnesses to neutralize claims of influence).

The court will narrow the scope of discovery on this topic somewhat, however. Plaintiffs' allegation is that Dr. Ayres improperly prescribed a Biogen product. Evidence of financial relationships with Biogen is relevant to the question of whether the prescription of a Biogen drug was influenced by such relationships. Any financial relationships that Dr. Ayres might have had with pharmaceutical companies other than Biogen are not relevant. The court

will accordingly limit the scope of discovery to Biogen; UVNN is not required to produce information regarding receipt of payments or items of value from companies other than Biogen.

Taking a different tack, UVNN argues that Plaintiffs are seeking evidence of influence by relationships with drug companies without any "factual basis or support." (Doc. 101 at 3.) UVNN maintains that there is no such evidence and that Plaintiffs' discovery request is a fishing expedition. The court rejects that argument. Plaintiffs' request is based on more than mere speculation about what might be discovered. The Sunshine Act database shows that Dr. Ayres received limited funding and payments from Biogen in 2013 and 2014.

B. Proportionality

It is not enough that the requested discovery be relevant; Rule 26(b) also requires that it be proportional to the needs of the case. In making the proportionality determination, the court considers "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). The court is not required to make formal and explicit findings regarding each factor. *See Patient A.*, 2016 WL 880036, at *1 (citing *Meeker v. Life Care Ctrs. of Am., Inc.*, No. 14-cv-02101-WYD-NYW, 2015 WL 7882695, at *3 (D. Colo. Dec. 4, 2015)).

Here, it is unclear to the court precisely how important any alleged industry conflict might be to Plaintiffs' case. It appears unlikely that this issue is the centerpiece of Plaintiffs' claims. But Plaintiffs insist that the requested information will provide "support" for their claim that "the misdiagnosis of Ms. Mier, and the rush to administer powerful drugs, were improperly influenced" and that there was a deviation from the standard of care. (Doc. 99 at 2.)

Regarding the amount in controversy, the Amended Complaint does not demand a particular dollar figure other than to state that the amount in controversy exceeds $75,000. (*See* Doc. 8.) But the Amended Complaint does allege that Ms. Bertolini-Mier required more than six months of hospitalization and ongoing treatment since her discharge. (*Id.* ¶ 20.) The damages claim in this case is therefore potentially significant.

UVNN argues that collecting the evidence to satisfy Plaintiffs' discovery request would constitute an undue burden. (Doc. 96 at 8.) Plaintiffs assert that the requested evidence is easy to obtain because UVNN had an accountant who tracked relevant information and because the relevant records are at UVNN's building. (Doc. 99 at 5.) Although UVNN continues to assert in its reply that the requested discovery is "unduly burdensome" (Doc. 101 at 4), they do not offer any more detailed response to Plaintiffs' suggestion that the information is readily available via the UVNN accountant and in records at the UVNN building.

Having considered all of the proportionality factors, the court concludes that the requested discovery—limited to Biogen as described above—is proportional to the needs of the case.

Conclusion

Defendant UVNN's Motion for Protective Order (Doc. 96) is GRANTED insofar as UVNN is not required to produce information regarding receipt of payments or items of value from companies other than Biogen. The motion is otherwise DENIED.

Dated at Rutland, in the District of Vermont, this 4 day of November, 2019.

Geoffrey W. Crawford, Chief Judge
United States District Court